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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/758,291	01/14/2004	Alexei Brooun	SYR-MVAS-5001-C1	5544

32793 7590 03/13/2007  
TAKEDA SAN DIEGO, INC.  
10410 SCIENCE CENTER DRIVE  
SAN DIEGO, CA 92121

EXAMINER
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NASHED, NASHAAT T

ART UNIT	PAPER NUMBER
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1656

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/13/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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<b>Office Action Summary</b>	<b>Application No.</b> 10/758,291	<b>Applicant(s)</b> BROOUN ET AL.	
	<b>Examiner</b> Nashaat T. Nashed, Ph. D.	<b>Art Unit</b> 1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,4,5,7,10,11,13,17 and 19-24 is/are pending in the application.  
     4a) Of the above claim(s) 17 and 19-23 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 24 is/are allowed.
- 6) ☒ Claim(s) 1,4,7,10,11 and 13 is/are rejected.
- 7) ☒ Claim(s) 5 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
     a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

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The application has been amended as requested in the communication filed, January 24, 2007. Accordingly, claims 2, 3, 6, 8, 9, 12, 14-16, and 18 have been canceled, claim 24 has been added, and claims 1, 5, 7, and 11 have been amended. Claims 17, and 19-23 remain withdrawn from further consideration for being directed to non-elected subject matter.

Claims 1, 4, 5, 7, 10, 11, 13, and 16 are under consideration in this Office action.

The restriction requirement has been traversed in the previous Office action mailed July 24, 2006. In addition applicants were advised on the rejoinder policy in view of *in re Ochiai*. See the previous Office action mailed July 24, 2006. The examiner has no further comments regarding the restriction requirement.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s). In particular, 37 CFR 1.821, which states:

(d) Where the description or claims of a patent application discuss a sequence that is set forth in the "Sequence Listing" in accordance with paragraph (c) of this section, reference must be made to the sequence by use of the sequence identifier, preceded by "SEQ ID NO:" in the text of the description or claims, even if the sequence is also embedded in the text of the description or claims of the patent application.

Thus, each time the specification refers to a specific MvaS protein, the protein name must be accompanied by SEQ ID NO: 1 (see for example see Figures description of Figures 3-5 starting at page 11, and the headings for Tables 2-4.

In response to the above, applicants made an earnest effort to perfect their compliance with the sequence rules, but their effort failed short. The Table of atomic coordinates in Figure 3 represent a disclosure of a linear amino acid sequence of more than four amino acid sequence, which should be disclosed in the sequence listing as SEQ ID NO: 1. Thus, the Table of atomic coordinate should have either a Table heading identifying the protein by name and amino acid sequence. Alternatively, applicants may amend the Figure description of Figure 3 to insert the amino acid sequence. In addition applicants, must amend the description to Figure 4 and 5 by inserting the amino acid sequence identification number.

Claim 5 is objected to under 37 CFR 1.75 as being a substantial duplicate of claim 24. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k).

The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 4, 7, 10, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the prior Office action, mailed 7/24/06.

In response to the above rejection, applicants traverse the rejection on the following ground: (a) the application discloses enough to convince one of ordinary skill in the art the inventor possessed the claimed invention; and (b) applicant was in possession of the genus because the claimed subject matter defined structurally.

Applicants' arguments filed 1/24/07 have been fully considered, but they are found unpersuasive. In the previous Office action, the examiner made it crystal clear that a crystal of the amino acid sequence of SEQ ID NO: 1 in space group  $P2_12_12_1$  having unit cell dimension  $a = 68.7$ ,  $b = 79.6$ , and  $c = 150.2$  Angstroms,  $\alpha = \beta = \gamma = 90$  degrees is fully described in the specification that one of ordinary skill in the art would have recognized that applicants have possession of said crystal. Applicants should note that claim 5 is no longer included in this rejection any more. Applicants', however, were not in possession of the genus claims such as any crystal of SEQ ID NO: 1 grew under any set of crystallization conditions or any method of crystallizing the polypeptide of SEQ ID NO: 1 or method of obtaining a specific crystal grew under any crystallization conditions. The disclosure of a well-known method for screening crystallization conditions is no indication that applicants were in possession of the entire genus of crystals or method of crystallization. In addition, Table 5 are not specific conditions wherein any crystal grew. Table 5 contains ranges of concentration of additives and pH's of the screen for crystal. Obtaining the specific crystal, which diffracts X-ray is the accomplishment and the invention in this application. Of the alleged numerous crystals taught in the specification, none other than that indicated above is described in sufficient details that would allow one of ordinary skill in the art to conclude applicants were in possession of the entire genus. Thus, the claims remain rejected for the reasons stated above.

Claims 1, 4, 7, 10, 11, and 13 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the prior Office action, mailed 7/24/06.

In response to the above rejection, applicants traverse the rejection on the following ground: (a) the application discloses enough to convince one of ordinary skill in the art the inventor possessed the claimed invention; and (b) applicant was in possession of the genus because the claimed subject matter defined structurally.

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Applicants' arguments filed 1/24/07 have been fully considered, but they are found unpersuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning supported by art why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely assert that the enablement requirement is met if the description enables any mode of making and using the invention. Also, they assert that the specification discloses a variety of crystals grew under variety of conditions. Applicants are invited to point out to a location in the specification where a crystal other than that identified in new claim 24 has been observed. Table 5 at page 20 of the specification does not show what the applicants assert. Applicants make no effort to explain why they consider the disclosure of single crystal of the polypeptide of SEQ ID NO: 1 and a method specific method of obtaining said crystal to be enabling with respect to any crystal of the polypeptide of SEQ ID NO: 1 or any method of making any crystal of the polypeptide of SEQ ID NO: 1. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

Allowable subject matter:

- (1) New claim 24 is allowed.
- (2) Claim 5 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. In amending claim 5, applicant should make sure the amended claim is not going to have the same scope as that of claim 24. The incorporation of the embodiments of claim 1 to claim 5 would produce a claim identical to that of claim 24.

Claims 1, 4, 7, 10, 11, and 13 remain rejected for the reasons set forth above.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

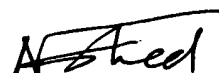
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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTWTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen K. Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Nashaat T. Nashed, Ph. D.  
Primary Examiner  
Art Unit 1656